

Odidi et al.  
Application No. 09/845,497  
Docket No. 9577-25 LAB

This listing of claims will replace all prior versions and listings of claims in the application:

**Listing of Claims:**

**Claim 1** (Currently amended) An extended release pharmaceutical active formulation comprising:

- a capsule, tablet, or pellet, or bead comprising about 5-95% by weight pharmaceutical active and an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet or pellet, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

**Claim 2** (Cancelled).

**Claim 3** (Cancelled).

**Claim 4** (Cancelled).

**Claim 5** (Cancelled).

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Claim 6 (Previously presented) The formulation of claim 1, wherein said compression aid is present in an amount of up to about 60% by weight.

Claim 7 (Previously presented) The formulation of claim 1, wherein said extrusion aid is present in an amount of up to about 50% by weight.

Claim 8 (Previously presented) The formulation of claim 1, wherein said formulation additionally comprises excipients, lubricants, binders or glidants.

Claim 9 (Previously presented) The formulation of claim 1, wherein said polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof.

Claim 10 (Cancelled).

Claim 11 (Original) The formulation of claim 1, wherein said polymeric film comprises shellac or zein.

Claim 12 (Cancelled).

Claim 13 (Cancelled).

Claim 14 (Cancelled).

Claim 15 (Previously presented) The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of risedronate, alendronate, riluzole, and sulfonylureas.

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**Claim 16 (Original)** The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of bioactive peptides, antitumor agents, antibiotics, antipyretic analgesic antiinflammatory agents, antitussive expectorants, sedatives, muscle relaxants, antiepileptics, antiulcer agents, antidepressants, anti-allergic agents, cardiotonics, antiarrhythmic agents, vasodilators, hypotensive diuretics, anticoagulants, hemolytics, antituberculosis agents, hormones, narcotic antagonists, bone resorption suppressors and angiogenesis suppressors.

**Claim 17 (Previously presented)** An extended release pharmaceutical active formulation comprising:

- a capsule, tablet, pellet or bead of about 5-95% by weight pharmaceutical active, about 0-60% by weight pharmaceutical compression aid selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar, and about 0-50% by weight pharmaceutical extrusion aid,

- an encasement coat comprising one or more layers of a polymeric film encasing said capsule, tablet, pellet or bead, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

**Claim 18 (Cancelled).**

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Claim 19 (Cancelled).

Claim 20 (Cancelled).

Claim 21 (Previously presented) The formulation of claim 17, wherein said polymeric film is a polymer selected from the group consisting of cellulose esters, polyvinyl acetate phthalate, methacrylic acid copolymers and any mixtures thereof.

Claim 22 (Original) The formulation of claim 15, wherein said polymeric film further comprises an agent selected from the group consisting of plasticizers, antitacking agents, colorants and mixtures thereof.

Claim 23 (Previously presented) An extended release pharmaceutical active formulation comprising:

a capsule, tablet, pellet or bead of pharmaceutical active comprising;

- about 5-95% by weight pharmaceutical active;
- about 0-60% by weight pharmaceutical compression aid;
- about 0-50% by weight pharmaceutical extrusion aid; and
- an encasement coat comprising one or more layers of a polymeric film encasing said pharmaceutical active, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer comprising polyethylene glycol,
- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

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**Claim 24 (Previously presented)** The formulation of claim 1, wherein greater than 80% of said pharmaceutical active is released in one hour when tested in a USP apparatus at 100 rpm in 900ml degassed water and 37°C.

**Claim 25 (Previously presented)** The formulation of claim 1, wherein less than about 20% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 75 rpm in 900ml simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and greater than 80% of the pharmaceutical active is released in one hour when tested in a USP apparatus at 75 rpm in 900ml simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C.

**Claim 26 (Previously presented)** The formulation of claim 1, wherein the tablet or pellet is made by direct compression.

**Claim 27 (Original)** The formulation of claim 15, wherein the release of the pharmaceutical active exhibits a lag phase (time) and after which release is extended over 12 hours or 24 hours after administration.

**Claim 28 (Currently amended)** The formulation of claim 1, wherein the capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 24[[4]] hours when tested in a USP apparatus at 100 rpm in 900ml degassed water and 37°C.

**Claim 29 (Currently amended)** The formulation of claim 1, wherein said capsule, tablet, pellet or bead demonstrates extended release characteristics of greater than 24[[4]] hours when tested in a USP apparatus at 75 rpm in 900mls simulated gastric fluid (pH 1.2 phosphate buffer) and 37°C and demonstrates

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extended release characteristics of greater than 24[[4]] hours when tested in a USP apparatus at 75 rpm in 900mls simulated intestinal fluid (pH 7.5 phosphate buffer) and 37°C.

Claim 30 (Original) The formulation of claim 21, wherein pharmaceutical active release exhibits a lag phase (time) after which release is extended over 12 hours or 24 hours when administered to humans or animals in the presence of food.

Claim 31 (Currently amended) A method for making an extended release pharmaceutical active formulation comprising:

- compressing about 5-95% by weight pharmaceutical active into a capsule, tablet, or-pellet, or bead with an aid selected from the group consisting of a pharmaceutical compression aid and a pharmaceutical extrusion aid and mixtures thereof, wherein said compression aid is selected from the group consisting of lactose, cellulose, dibasic calcium phosphate dihydrate, calcium sulfite dihydrate, tricalcium phosphate and compressible sugar;

- encasing said capsules, tablets, pellets, or beads in an encasement coat comprising one or more layers of a polymeric film, said encasement coat being non-permeable and soluble in a pH of above about 5.0 and comprising about 5 up to less than 50% by weight polymer and about 0.5%-30% by weight plasticizer of polyethylene glycol,

- wherein said formulation provides over 12 hours of extended release of said active in the bloodstream.

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Claim 32 (Previously presented) The method of claim 31, wherein said pharmaceutical compression aid is present in an amount of up to about 60% by weight and said pharmaceutical extrusion aid is present in an amount of up to about 50% by weight.

Claim 33 (Cancelled).

Claim 34 (Previously presented) The formulation of claim 1, wherein said pharmaceutical active is selected from the group consisting of glyburide, chlorpropamide, tolbutamide, glimepiride, acarbose, alglucerase, miglitol, nateglinide, pimagidine, pioglitazone, pramlintide, repaglinide, rosiglitazone, troglitazone, hypoglycemic benzenesulfonamido pyrimidines, buformin and phenformin.